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Review Article

HOW PHARMACOVIGILANCE PLAY CRUCIAL ROLE IN HEALTH CARE SYSTEM AND PvPI IN INDIA

Ms.Sonali R. Chavan [1], Ms.Archana Gawade[2]

1. Department of Pharmacology, MET's Institute of Pharmacy, Bhujbal knowledge City, Adgaon, Nashik 422-003 Maharashtra, India and Advance Diploma in Pharmacovigilance and clinical research Scholar from Elite institute of Pharma Skills Pune.
2. Managing Director, Elite Institute Of Pharma Skills, Pune

Address for correspondence:

Ms.Sonali R. Chavan, Department of Pharmacology, MET's Institute of Pharmacy, Bhujbal knowledge City, Adgaon, Nashik 422-003 Maharashtra, India and Advance Diploma in Pharmacovigilance and clinical research Scholar from Elite institute of Pharma Skills Pune
E-mail- chvansonali47@gmail.com

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ABSTRACT

The ultimate aim of this paper to discuss detail about Pharmacovigilance, its importance and the challenges that face in PV. This paper gives basic idea about the terminologies that involve in Pharmacovigilance like adverse drug reactions, adverse event, rechallenge, dechallenge, serious adverse event, expected and unexpected adverse drug reactions etc. The paper describes the Pharmacovigilance programme in India and its regulation by various government body and health authority, heath care centre. The reader can understand the necessity of PV in health care system and effect of its on large number of population in the world. The possible future aspect of Pharmacovigilance is written in brief. There is huge need of Pharmacovigilance in medicine system as it affects the health of large number of population. Drug passes through pre-clinical and clinical trial where drug exposed to less number of people (subject under study). When it comes into market it administered by large number of population globally. There is high risk of developing health related hazards to patient. Proper monitoring and assessment of such unwanted drug effect are come under Pharmacovigilance.

KEY WORDS: Pharmacovigilance, PvPI, ADRs, CDSCO, serious adverse drug event.

INTRODUCTION:

Pharmacovigilance having great importance in healthcare field, as it plays crucial role in assessment, monitoring and detecting drug interaction, its therapeutic activity on human body. Drug is intended to treat, prevent and diagnose the disease condition. On another side there is huge risk of developing any unwanted adverse drug reaction in patients that may lead to serious harm. For this reason there is need to safety check for monitoring such ADR in patients. For assessing drug safety and monitoring its adverse drug reaction throughout their life span this concept is called as post marketing surveillance. Pharmacovigilance involve in detection, assessment, understanding and preventing the adverse drug reaction. [1]

In 1961 the Pharmacovigilance concept were officially introduced with case report by the Australian doctor who initially correlate the phacomelia and thalidomide drug which used in pregnant women. These drugs were used as antiemetic and sedative. [2] In the year 1968 WHO were announced the International Drug Monitoring event as a pilot study whose aim was to collect central data on adverse drug reactions. Priority of this program was to detect early signal of PV. The term PV was introduced by some French groups of pharmacologist and toxicologist person's. They define pharmacology as an "assessment of risk of side effect potentially associated with drug treatment" [3].

Pharmacovigilance involve the collecting all the data from health care profession person and patients. Monitoring , assessing , and evaluating of these all information for ADR, or any hazards relateded with drugs, blood products, vaccine any medical devices, biological products etc. Thus it is helpful in preventing any harm to the population. That led to improve the maximum drug safety. The pharmaceutical and biotechnology industries must have to monitor, evaluate and manage the drug risk thoroughly. The drug must be kept in observation and monitor even after it comes into market, hence post marketing terminology evolve. [4]

PV mainly recognizes for ADRs. Adverse drug reaction is nothing but the noxious and unintended effect of drug which occurs at doses that dose used for normal therapeutic purpose in disease treatment. [5] The analysis of risk benefit of drug is therefore very important. The severe level of morbidity, mortality is serious problems that need to be controlled. There is no guarantee of safety even after pre clinical and clinical stages, when drug come into market the large number population take that medicines. In clinical trial countable number of people exposed to study and hence data showing less number of side effect. Pharmacovigilance consider all data, investigate all the reports and evaluate the relationship between drug and adverse drug reactions. The drug regulatory system maintains proper working and monitoring of the PV system. These systems work during drug development study and also even after post marketing of the drug [6]. In drug practice, their safety and monitoring various body involve such as, government, health care system, hospitals, pharmacy, poison information centre, patients, media etc.[7] In India very few drug have discovered so there is not strong restriction to have PV system to detect the ADRs of drug after marketing. The drug that is marketed is in use

from several years before introducing to India, this drug was used by industries and regulatory authorities to evaluate the drug safety and step taken for preventing future consequences.

The staring of new patient regime the pharmaceutical and biotechnology industries has a trade related intellectual property rights and services prohibit the use of products without license from innovatory industry. This make realizing to companies about new regime, that is already commence to investments of substantial resources for developing new drug that is helpful for both Indian and foreign market. This lead to develop scope for the new drug evolution by Indian companies based on pre clinical and data will be generated in future. In this case the Indian companies not need to count the data based on experience of other market to the safety of drug by PV system in India. This will be very appropriate to monitor the ADRs of drug that first launched in India. [1]

The seriousness of ADRs:

The several studies that were performed all over the world have described the ADRs decreases the quality of life, it lead to increase hospitalization of the patients, and elevate the mortality rate. It is 4th to 6th major cause of mortality among the population according to landmark study that conducted in 1998 in USA and this is the major reason behind hospitalization about 3 to 7 percent. More than 50% of these ADR were not identified by the physicians and it is responsible to cause death of fifteen people out of 1000. Financially it is very expensive to health care system. Without long term study, the post marketed drug, patient self medication this lead to highest risk of explosive itself to ADRs. The OTC medicines are widely used over the prescription medicine by the patient hence it is at peak of risk to develop the adverse drug reaction in patients. [8]

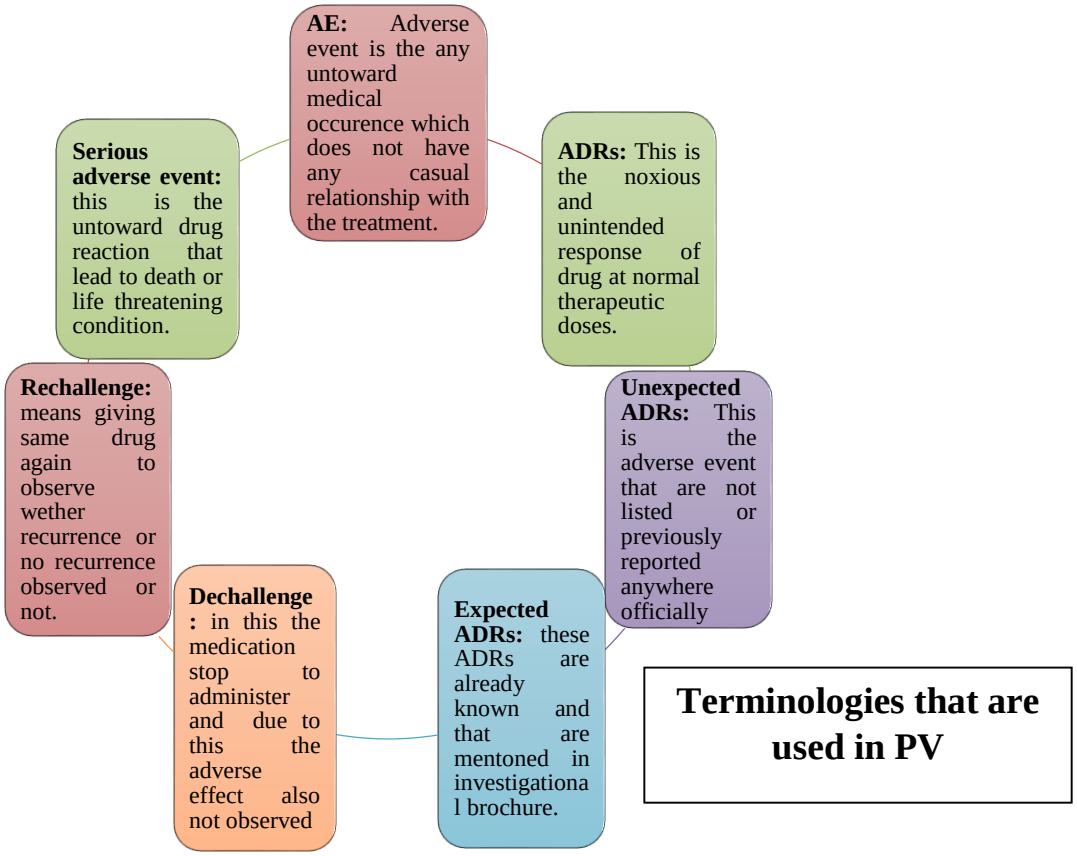

Fig 1: diagrammatic presentation of the terminologies those are associated with various adverse drug reactions in PV.

The detail about PvPI (Pharmacovigilance programme In India):

The various government body that run the PvPI program in India are, CDSCO, government of India under association of Indian Pharmacopeia commission and the director general of health services etc. This program aim is to protect health of the patient by iniating drug safety. This program initiated and controlled by the pharmacopeia commission that is located at Ghaziabad name as NCC i.e., NATIONAL CORDINATING CENTRE. This PvPI program were initiated in July 2010 with AIIMS which having objective to monitor ADRs in India and look after safety of public. [9]

Objectives of the Pharmacovigilance programme in India: [9]

No.	Objectives
1	To detect the new signal adverse drug reactions from case report of patient.
2	To evaluate the benefit risk ratio of the post marketed product
3	To establish evidence related to safety of medicines
4	To talk about safety information with stakeholders to decrease risk
5	To establish national centers for transferring information related to drug ADRs.
6	To give support to the PV centers and give training to them.

The challenges that commonly seen in PvPI are:

The major challenge that faces in PvPI is underreporting of ADRs due to highest work load on health care system, missing of medical expertise at the time of drug administration and missing of proper guidance about Pharmacovigilance. Another challenges includes pharmacist should be empowered to elevate the ADRs reporting. The missing of proper regulatory observation towards the ADRs and inadequate training to health care personnel that leads to affect working of PV. Drug related problems are widely used injectibles, maximum use of antibiotics, not enough guideline for treatment, inappropriate prescribing, training and also use of herbal medicine, OTC medicines etc. some diseases like T.B and HIV required multiple drug treatment so there is high risk of developing ADRs, drug interactions that result into serious health hazards. [10, 11, 12]

Importance of Pharmacovigilance:

There is need to advance medicinal use in treatment and control of several disease conditions, that causes ADRs in patients. Various drugs that cure the disease but with this they also produces some untoward effect or interact in unwanted way so it cause harm to health and showing effect that are not desire to cause. [13] Once drug come intro market that consume by number of population , in this step many drug have gone through limited duration of study for safety and efficacy on less number of subject that involve in study. So here need of PV develop that helpful for early detection of ADRs in patients groups in the population and invent certain measure to regulate and control such health related risk. [14]

Future outcome of the PV in India:

As this is broad concept to explain, which associated with the herbal, chemical, biological and medicinal products and devices.[15] the initial report of suspected medicine is collected from the heath care personnel's and the person who affected with this adverse effect. Based on this data the necessary steps are taken to prevent on unwanted drug effect and spread awareness among people who consume such medications. The adverse effect that related with drug involves adverse events, drug interactions, poisoning, overdose, misuse of drug, serious adverse event [16]. The vaccine failure, concept of drug- drug interaction, medication error are also involve in Pharmacovigilance. PV practice is must in all medical related system in India that satisfies patient's health safety. Some of futures aspects regarding PV are necessary to practice in system of medicine are describe below: [17]

I. To promote and enhance the function of pharmaceutical manufacturers for ayurveda siddha and unani medicine.
II. To enhance and promote training and education.
III. To give strength to Ayurveda, Unani and Siddha system of medicine.
IV. To encourage the health care personnel for rational use of medicine.
V. To introduce an International coordinating database that provides information related with ADRs and adverse event and give support to signal detection.
VI. Help to transfer data and make easy to communicate data with related authority to identify the nature or adverse effect
VII. Establishing strong Pharmacovigilance reporting system
VIII. To make PV reporting mandatory
IX. To make single country adverse report and that can be used overall
X. To make timely inspection of Pharmacovigilance
XI. To make better way communication with multiple stakeholders.
XII. To enhance work flow of DCGI by providing well trained medical evaluator for PV.
XIII. To create separate database of post marketed drug adverse drug reactions for signal detection.
XIV. Make a list of all drugs that are new from each and every pharmaceutical industry.
XV. Give more attention to education and training for all the personnel that work in health care system.
XVI. To build network with pharmacopeidemologist, pharmacoenvironmentologist and the academicians etc.

CONCLUSION:

The aim of this review article is to give basic idea about the Pharmacovigilance and its regulation in India. The various terminologies, facts and regulatory body that associated for maintain the smooth work flow of PV is introduced here. The importance of Pharmacovigilance system in health care are described in the paper with

future aspects and challenges observed in PV. The reader can find out ADRs and how Pharmacovigilance play crucial role in controlling and recording these adverse drug reactions.

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